Trends and Developments

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RASS

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STUDIO LEGALE RINALDI E ASSOCIATI

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Introduction

This brief contribution is aimed at examining the main changes that have occurred during the last year in the medical device regulation that, in our opinion, best represent the main trends in Italy.

In particular, the Italian Government is engaged, on the one hand, in rationalising medical device expenditure while continuing to guarantee the highest quality of services provided through the national health system (the Servizio Sanitario Nazionale, SSN) and, on the other hand, in regulating the use of artificial intelligence and new technologies in accordance with EU principles.

Therefore, we will first analyse the so-called "payback" mechanism ("Payback") in light of two recent rulings by the Italian Constitutional Court (the "Court"), the rules governing the new Fund for Medical Devices and, then, the implementation of the Unique Device Identification System, ending with a brief review of the impact of the Regulation (EU) No 2024/1689 on medical devices.

The Italian Constitutional Court's Rulings on Medical Device Payback

In two separate rulings (Nos 139 and 140) issued on 22 July 2024, the Court confirmed the legitimacy of the rules governing Payback introduced in Law Decree No 78/2015 ("LD No 78/2015"), as amended by Law No 125/2015 (the "Payback Law").

Broadly speaking, medical devices are supplied to the SSN through competitive tenders issued by the Italian regions for all kind of devices such as prostheses, heart valves, bandages, syringes, patches, orthopaedic prostheses, etc.

Payback is intended to balance the various constitutional interests tied to the purchase of medical devices – such as the streamlining of public spending, the right to health of SSN patients, and private economic initiative – and consists of a monetary compensation owed by the companies supplying medical devices (the "medical device companies") to the SSN.

Under Article 9-ter of LD No 78/2015, the annual expenditure for medical devices by the regions is capped at an amount set by the Ministry of Health, and if this cap is exceeded, medical device companies are required to refund the amount in excess to the SSN. The list of medical device companies required annually to refund the amount in excess is set by the regions in accordance with para 9-bis of said Article.

As a matter of fact, only in 2022 did the Ministry of Health state the actual amount in excess to be paid back for the period 2015-2018. Unsurprisingly, this provoked a strong reaction on the part of the medical device companies, which claimed, also in court, that they should not be held responsible for the sum in excess spent by the regions, considering, inter alia, that this sum was not known when the tender was called/adjudicated and, in any case, the revenues generated by the sale of those devices had already been taxed without taking into account the sum to be refunded.

To minimise the financial impact of Payback on the medical device companies and to discourage further litigation, in 2023 new rules were issued by the Italian Government. Article 8 of Law Decree No 34/2023 ("LD No 34/2023") established a state fund allocated on a pro rata basis to the regions exceeding the cap in the period 2015-2018. Furthermore, a 52% discount on the due amount was set in favour of medical device companies that had not appealed against the regional measures issued under Article 9-ter,

paragraph 9-bis, of LD No 78/2015 or that had abandoned their lawsuits.

The Payback Law as well as the discount granted to medical device companies were submitted to the Court. In the above-mentioned rulings (Nos 139/2024 and 140/2024), the Court confirmed not only the validity of the Payback mechanism but also that of the discount granted to the medical device companies, which was not found to be disproportionate.

In particular, ruling No 139/2024, issued in response to an appeal filed by the Campania Region contesting Article 8, paragraphs 1, 2, 3, and 6 of LD No 34/2023, confirmed the constitutional unlawfulness of paragraph 3 of said Article 8, because it does not extend to all medical device companies the reduction to 48% of the quota established by the regional measures referred to in Article 9-ter, paragraph 9-bis of LD No 78/2015. This provision is indeed in conflict with the principle of equality established in Article 3 of the Italian Constitution and with the principle of balance of financial relations between the State and the regions under Article 119 of the Italian Constitution.

On the other hand, ruling No 140/2024, issued upon request of the Lazio Regional Administrative Court, stated the constitutional legitimacy of Article 9-ter of Decree-Law No 78/2015 and, consequently, of Payback also for the period 2015-2018. Although the Court noted some critical issues, Payback was found not to be in conflict with the Italian Constitution and, as a consequence, the appeal of the Lazio Regional Administrative Court was dismissed. In its ruling, the Court held that a limitation to the contractual autonomy of private operators can be established by the Government when it is intended to pursue "social utility" and is reasonable and proportional.

In the Court's vision, Payback is (i) "not unreasonable, since it imposes on companies a solidarity-based contribution that is justified by the need to ensure the supply of medical devices necessary for the protection of health, especially in a highly critical general economic-financial situation, which does not allow the budgets of the State and the regions, financed by the community resources, to fully cover the required expenses"; and (ii) not disproportionate, in light of the fact that the amount to be paid to the regions was reduced to 48% of the amount originally due and that, following Court ruling No 139/2024, this provision was extended to all medical device companies, regardless of whether they had litigation pending in their region.

The Fund for Medical Devices: a New Form of Contribution in Addition to Payback

In a Decree issued on 29 December 2023, published on 9 February 2024 (the "2023 Decree"), the Ministry of Health set out the criteria and methods for financing the Fund for Medical Devices (the "Fund").

More specifically, in enacting Article 28 of Legislative Decree No 137/2022 (which implements European Regulation No 745/2017 on medical device regulation) and Article 24 of Legislative Decree No 138/2022 (which implements European Regulation No 746/2017 on in vitro medical device regulation), the 2023 Decree established that, with effect from 2024, each year between 1 November and 31 December, companies producing or distributing medical devices and large medical equipment as well as in vitro diagnostic medical devices shall pay the Ministry of Health a sum equal to 0.75% of the turnover of the previous financial year generated from the sale of

medical devices (including large medical equipment and in vitro diagnostic medical devices) to the SSN.

In addition, by 31 December of each year, these medical device companies are required to submit to the Ministry of Health a declaration concerning the value of their turnover, net of VAT, resulting from the sale of said medical devices.

The Fund will be mainly used for:

- financing the activities of the national programme for the assessment of medical devices (health technology assessment);
- market surveillance, with particular reference to the examination or testing of medical devices and in vitro diagnostic medical devices;
- database management;
- activities related to the tracking of medical devices;
- clinical investigations;
- activities conducted by the National Observatory of Medical Device Prices;
- the implementation and management of information systems required for the governance of medical devices, including information systems supporting market surveillance, as well as registers of implantable medical devices;
- financing activities carried out by the Ministry of Health for the registration of manufacturers, authorised representatives and importers on EUDAMED;
- setting out guidelines containing rules, technical guides, codifications, classifications and standards necessary to ensure the collection, storage, consultation and interchange of health data involving medical devices; and
- the promotion and implementation of health and socio-health services based on data on the use of medical devices.

The Unique Device Identification System

With the aim of ensuring the safety of medical devices in the post-market phases, helping to reduce medical errors and supporting the fight against counterfeit devices, the Ministry of Health issued two Decrees (dated 11 May 2023 and published in the Italian Official Gazette on 11 July and 18 July 2023), which regulate the registration and storage of the Unique Device Identifier (UDI) of medical devices and in vitro diagnostic medical devices.

Under Regulations (EU) No 2017/745 (the medical device regulation, MDR) and No 2017/746 (the in vitro diagnostic medical device regulation, IVDR), the UDI is "a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market".

All healthcare institutions, and healthcare professionals who do not carry out their professional activity in the context of a healthcare institution, are required to electronically register and store the UDIs of medical devices they have received if these belong to class III or IIb implantable; and of in vitro diagnostic medical devices they have received if these belong to class D. There are no obligations for any devices belonging to the other risk classes, but the option exists to register and store UDIs on a voluntary basis.

Medical devices that are CE-marked in accordance with the MDR and in vitro diagnostic medical devices that are CE-marked in accordance with the IVDR are subject to the registration obligation.

The registration and storage of UDIs must be done electronically and healthcare institutions, and healthcare professionals who do not carry

out their professional activity in the context of a healthcare institution, may request medical device companies, at the time of purchase, to electronically submit the UDIs of each device.

With regard to the storage time of UDIs, the Decrees provide for a different regime for implantable devices that accords greater protection. For such devices, information must be stored for a minimum period of 15 years from the time of registration. For non-implantable devices, the minimum storage period is ten years.

The Impact of the AI Act on Medical Devices

On 12 July 2024, Regulation (EU) No 2024/1689 (the "AI Act"), aiming to "improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union", was published in the Official Journal of the European Union and entered into force on 1 August 2024.

The AI Act adopts a risk-based approach to regulation, classifying AI systems as unacceptable, high, medium or low risk. Systems considered to have unacceptable risk are prohibited. For those classified as high, medium or low risk, the regulatory requirements vary according to the level of risk.

The application of the AI Act (from 2 August 2026, with some exceptions) will have a significant impact on medical device companies manufacturing or distributing devices based on AI systems, and in particular AI systems defined as "high risk".

Software with a medical purpose is already regulated in Europe as a medical device by the MDR and the IVDR, and requires full assessment before it can be placed on the market. Indeed, Recital No 19 of the MDR clarifies that the "software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device", and Recital No 17 of the IVDR contains the same clarification in relation to in vitro diagnostic medical devices.

The implementation of the AI Act will make it crucial for medical device companies to determine whether the software they use (be it the device itself or a security component of a device) qualifies as an AI system, defined by the AI Act as a "machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments".

More specifically, medical device companies will have to determine whether the software they use can be defined as a high-risk AI system, as most of the obligations provided for by the AI Act fall on providers of high-risk AI systems.

Article 6 of the AI Act classifies an AI system as high-risk if it fulfils both of the following conditions:

- The system is intended to be used as a safety component of a product, or is itself a product, covered by the EU harmonisation legislation listed in Annex I.
- The product contains an AI system safety component or is itself an AI system and therefore is required to undergo a third-party conformity assessment before being released

for sale or use, pursuant to the EU harmonisation legislation listed in Annex I.

It should be noted that Annex I of the AI Act lists both the MDR and the IVDR, and that, according to the MDR, all devices belonging to the risk classes IIa, IIb and III are subject to conformity assessment by a notified body, pursuant to Annex IX of the MDR.

Therefore, for those kinds of AI devices that fulfil both of the above-mentioned conditions, eg, endotracheal tubes (class IIa), X-ray devices (class IIb), articular prostheses and heart valves (class III), medical device companies will have to verify compliance both with the requirements already set out in the MDR and with the requirements of the AI Act.